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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/079,874 05/15/98 BILLING-MEDEL

P 6106.US.P1

023492
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HM12/0731

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/31/01

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/079,874

Applicant(s)

Billing-Medel

Examiner

Karen Canella

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 22-54 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 22-54 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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Response to Amendment

1. Claims 1-9 and 17-19 have been canceled. Claims 22-54 have been added. Claims 22-54 are pending and under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Maintained

3. Newly added claims 22-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art, for the reason of record stated in the office action of Paper No:13, namely that the specification provides no objective evidence linking the detection of the claimed polynucleotides with the diagnosis or detection of urinary tract disease. Further, although the specification teaches that the claimed polynucleotides are expressed in urinary tissue libraries from normal and diseased tissues, there is no reason to believe that these polynucleotides could be used as a marker for metastatic urinary tract cancer (pg. 3, lines 4-6 of Paper No. 13), as it is well known in the art that metastatic cells have altered patterns of gene expression in comparison with non-metastatic precursor cells. For instance, normal and non-invasive breast cancer cells are positive for E-cadherin expression, while metastatic breast cancer cells are negative (Oka et al, Cancer Research, 1993, Vol. 53, pp. 1696-1701). Therefore, it cannot be predicted that the claimed polynucleotides would be expressed in metastatic cells from the urinary tract, therefore, one of skill in the art would be subject to undue expectation without reasonable expectation of success in order to use the claimed polynucleotides.
4. Further, in the event that applicants are able to overcome the rejection under 35 U.S.C. 112, first paragraph, supra, the specification, while being enabling for SEQ ID NO:1-12, does not reasonably provide enablement for polynucleotides having 95% identity over the full length of

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SEQ ID NO:1-12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Newly added claims 22-30 are drawn to methods of detecting the presence of a target polynucleotide comprising contacting a test sample with a purified polynucleotide having at least 95% identity over the entire length to SEQ ID NO:1-12. Applicant has substituted claims encompassing 95% sequence identity over the full length for the previous claims drawn to 70% sequence identity in order to obviate this rejection. Clearly, as the specification has not taught a use for polynucleotides consisting of SEQ ID NO:1-12, it has enabled the scope of claims drawn to variants of SEQ ID NO:1-12. As stated in paragraph 6 of Paper No. 13, the specification does not teach how to use these variant polypeptides for the detection of any disease as these variant polypeptides would not necessarily be found in urinary tract tissue. Further, as stated in paragraph 6 of Paper No. 13, the specification does not teach how to make, or anticipate, the sequences of the variants SEQ ID NO:1-12 which would be found in urinary tract tissues. One of skill in the art would be forced into undue experimentation, without reasonable expectation of success in order to practice the broadly claimed invention.

New Grounds of Rejection

5. Newly added claims 43-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 43-45 state SEQ ID NO:1-12 and degenerate codon equivalents thereof. Degenerative codon equivalents are in reference to a polynucleotide encoding a protein and have no meaning when applied to polynucleotides consisting of EST sequences where an open reading frame or cDNA encoding a protein has not been set forth in the claim, such as "polynucleotides encoding SEQ ID NO:X, and degenerative coding sequences thereof".

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6. All other rejections and objections as stated in Paper No. 13 are withdrawn.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

July 30, 2001

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